APR 25 2008

K080743

510(k) Summary

I. GENERAL INFORMATION

Applicant's Name and Address:	Smiths Medical MD, Inc. 1265 Grey Fox Road St. Paul, MN 55112
Contact Person:	David H. Short Director of Regulatory Affairs and Design Assurance
Common/Usual Name:	Lockbox
Proprietary Name:	LockBox for CADD®-Solis Ambulatory Infusion Pump
Equivalence Device Comparison:	LockBox with Syringe Holder

II. DEVICE DESCRIPTION

The LockBox is an accessory to the CADD®-Solis ambulatory infusion pump. It is a plastic enclosure for the CADD®-Solis ambulatory infusion pump when it is attached to commercially available medication reservoir. The reservoir may be a flexible IV bag up to 500 mL in size or a syringe up to 60 mL. The Lockbox may be attached to a CADD-Prizm Polemount Bracket.

III. INTENDED USE OF THE DEVICE

The LockBox is intended to hold the CADD®-Solis infusion pump and provide reasonably secure access to the medication reservoir or syringe contained within.

V. SUMMARY OF STUDIES

A. Functional Testing

The LockBox was subjected to verification and validation testing as well as human factors usability testing. All tests performed demonstrate the LockBox meets the acceptance criteria for the safety and performance requirements set by the LockBox specifications.

B. Clinical Studies

Human clinical studies were deemed not necessary to evaluate the safety or effectiveness of the LockBox.

C. Conclusions Drawn from the Studies

Based upon the information provided, LockBox is safe, effective and performs to established specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 25 2008

Mr. David H. Short
Director of Regulatory Affairs and Design Assurance
Smiths Medical MD, Incorporated
1265 Grey Fox Road
St. Paul, Minnesota 55112

Re: K080743
Trade/Device Name: LockBox for CADD® -Solis Infusion Pump
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MRZ, FRN
Dated: April 18, 2008
Received: April 21, 2008

Dear Mr. Short:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

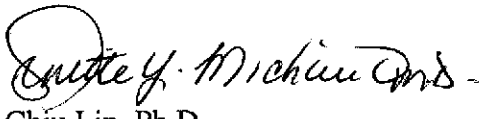
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SMITHS MEDICAL MD, INC.
510(k) Premarket Notification
LockBox for CADD®-Solis Infusion Pump

Indications for Use

510(k) Number: K080748

Device Name: **LockBox for CADD®-Solis Infusion Pump**

Indications for Use:

"The LockBox is a plastic enclosure designed to hold a CADD®-Solis infusion pump and a medication reservoir or syringe."

Prescription Use ___X___ OR Over-The Counter Use _____Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080748